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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,380	07/29/2003	Kirk Edward Vandezande	101384-22	6539

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NORRIS, MCLAUGHLIN & MARCUS
875 THIRD AVE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER	
ZHOU, SHUBO	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
05/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,380	VANDEZANDE, KIRK EDWARD	
	Examiner	Art Unit	
	SHUBO (Joe) ZHOU	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-14 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-14 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and request for reconsideration filed 3/5/09 are acknowledged and the amendment has been entered.

Claims 1-2, 4-14 and 22 are presently pending and under consideration.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-14 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Note that the rejection with regard to the method claims is reiterated from the previous Office action with modification in view of recent court decisions including *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008).

Claims 12-14 and 22 are drawn to a method for determining an optimal genetic test order for diagnosing mutations relating to a disease comprising: a) generating a data set by: identifying known unique genetic mutations that relate to the disease and the frequency with which each mutation occurs in the population; identifying assays required to diagnose each of the mutations that relate to the disease; identify the average cost of each assay; and for each assay, identify the probability of a successful diagnosis of each of the mutations that related to the disease; b) maintaining the data set to include new data received on the mutations that relate to the disease, the frequency distribution of

mutations that relate to the disease and the assays required to diagnose the mutations that relate to the disease; c) applying at least one decision tree algorithm, wherein the at least one decision tree algorithm comprises: (i) generating at least two strategies using the assays within the data set; (ii) ranking the at least two strategies by calculating the strategy expected cost of the at least two strategies; d) identifying, from the ranked at least two strategies, the optimal genetic test order as the strategy with the lowest strategy expected cost ; and e) presenting the optimal genetic test order to a user via an output device.

The Supreme Court has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See Benson, 409 U.S. at 70 ; Diehr, 450 U.S. at 192 ; see also Flook, 437 U.S. at 589 n.9 ;Cochrane v. Deener, 94 U.S. 780, 788 (1876). The same test is emphasized in *In re Bilski* as the only test for determining whether a claimed method is a statutory process. Id.

In the instant case, the claims only in the last step -- a step of presenting the result to a user -- refer to "an output device." However, there is no recitation and or limitations as to the particulars of the device in relation to the claimed method steps. In addition, the court has pointed out that the involvement of the particular machine/apparatus or transformation in a claimed process must not merely be insignificant extra-solution activity. See Flook, 437 U.S. at 590. In the instant case, the step of presenting the result

to a user falls into the insignificant extra-solution activity. Thus, the claimed method is not deemed to be tied to a particular machine or apparatus.

Moreover, there is no physical transformation of the claimed process because a process of mathematical data analysis involving a decision tree algorithm does not transform an article or physical subject to a different state or thing. Therefore, at least one embodiment of the claimed method is not a statutory process.

With regard to claims 1-2 and 4-11, drawn to computer readable medium and system for performing the method of claims 12-14 and 22, the rejection is withdrawn in view of the amendment, where the claims are amended to recite a step of presenting the optimal genetic test order to a user such that a useful, concrete and tangible result is produced. Furthermore, it is noted that applicant clearly states in the response filed 3/5/09 that the computer readable medium claimed does not include carrier wave.

Claim Rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are amended to recite a "tangible computer readable medium." Applicant did not provide, and the Office was unable to find, adequate support therefor in the specification. While the specification gives certain examples of computer readable media including recordable type of media and transmission-type of media (see page 11 of 48), it does not adequately disclose "tangible" computer readable media.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER